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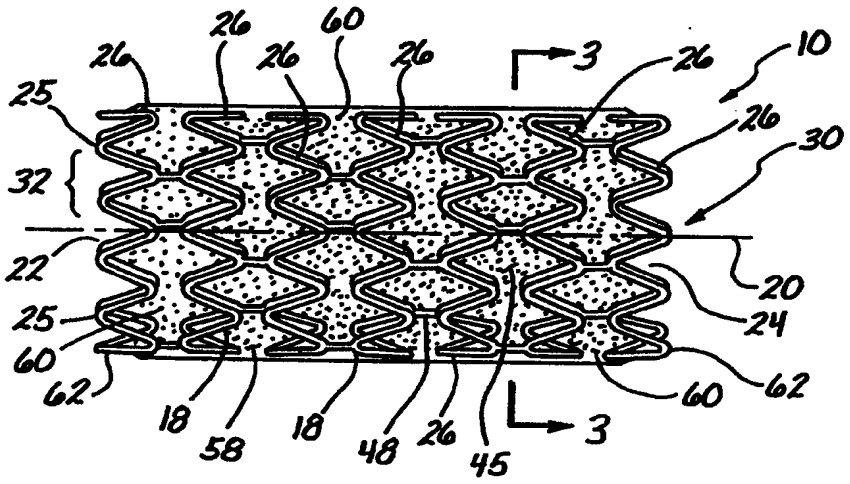

(57) Abstract

A radially expandable stent (10) and stent insertion device (12) for implanting the stent within a body passageway, such as an artery. The stent consists of a plurality of radially expandable cylindrical bands (26) which support a surrounding microporous coating (58). Each of the cylindrical bands are formed from a plurality of undulating sections (42) which are configured to expand uniformly and to impart a uniform stress on the surrounding coating. A plurality of linking members (48) join each pair of adjacent cylindrical bands that are oriented in quadrature positions around each circumference and about the successive pairs of adjacent cylindrical bands. The stent insertion device includes a balloon catheter (12) designed to perform angioplasty as well as implant the stent. The catheter device includes a catheter body (64) having an angioplasty balloon (72) at its distal end. An outer sleeve (76) is slidably supported about the catheter body to deliver and mount the stent on the balloon after the angioplasty procedure is complete. A method for using the balloon catheter device of the present invention is also disclosed.

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MICROPOROUS STENT AND IMPLANTATION DEVICE

Field of The Invention

This invention relates generally to intraluminal stent implants for restoring and maintaining the patency of a body lumen, and their insertion devices, and more particularly to a uniformly expandable and flexible stent for restoring and maintaining the patency of a vascular conduit and an associated insertion device.

Background of The Invention

Stents are commonly used to restore and maintain the patency of a damaged, injured or otherwise restricted body conduit or passageway. In particular, stents are commonly used to treat stenosis, stricture, and aneurisms, as well as other conditions. Stents, which are also commonly known as endoprostetheses, are typically placed within the body passageway through a mechanical transluminal implantation procedure. Typically, a surgical stent implantation device is percutaneously inserted within the body passageway to reinforce collapsing, partially occluded, weakened or abnormally dilated sections of the conduit. This procedure is commonly performed within the vascular system where a stent may be used to restore the patency of an artery or other blood vessel. However, stents may also be used within the urinary tract, the bial tract and the intestinal tract among other body passageways and conduits.

As mentioned, stents are often used in the treatment of diseased and damaged arteries and vessels. In a particular application, a stent may be used to repair or restore the patency in the artery or other blood vessel after angioplasty treatments. The angioplasty treatments are commonly used to compress obstructing material within a vessel into the vessel walls, or otherwise remove the obstructing material from the vessels walls to restore normal blood flow. These treatments produce injury to the vessel with healing that often results in restenosis or other tissue growth which can produce a new obstruction and re-narrowing of the vessel. In addition, the vessel may unexpectedly collapse and/or tear as a result of the treatment. Such a collapse or tear can cause a

sudden obstruction or leakage and have life threatening consequences for the patient. Thus, there is a need for a stent implanting device which can implant a stent immediately after angioplasty treatments.

If a stent is required during angioplasty treatment or soon after, the angioplasty device must first be removed and then the stent implantation device percutaneously inserted into the afflicted artery or vessel. The time required to remove the angioplasty device, as well as the time to insert the stent implantation device, can be quite long and must generally be done sequentially. This requires additional surgery time from both the patient as well as the operating team. The desirability and benefits of reducing surgery time are well known. In addition, if the vessel being treated is damaged during the angioplasty treatment, the need to immediately implant a stent may be critical. Thus, there is a need for a surgical device which can perform both angioplasty or similar treatments and implant a stent without having to be removed from within the vessel or other body conduit.

Restenosis and obstructing tissue regrowth are major problems when considering implanting a stent. This tissue regrowth extrudes through the openings in the implanted stent, causing a reduction in the passageway diameter. The obstructing tissue typically regrows through any openings within the stent. Fibrin and thrombus can also form on the stent structure. These growths often compete with the formation of the desirable smooth covering of neointimal cells over the inner walls of the stent.

In order to overcome the problems of restenosis and obstructing tissue regrowth, in addition to preventing blood or other fluid leaks from an injured passageway, a particular type of stent, known as a stent/graft has been developed. Stent/grafts have the advantage of almost fully covering the injured section of vessel wall with an outer covering which can stop blood leaks out of an injured vessel. Stent/grafts also reduce restenosis and the in-growth of obstructing tissue by preventing its growth past the sealing covering.

Stent/grafts are necessarily small in diameter to enable passage through the vascular system without damaging vessel walls during placement and implantation. The stent supporting structure must also be very flexible to pass

through the winding vascular system, yet structurally strong enough to support the vessel or other passageway without collapse. The stent should also be expandable so that it may be delivered in a reduced diameter state while on a small diameter catheter shaft and then expanded in-situ to support the vessel or other body passageway. However, the present stent/graft devices have a limited ability to expand. The outer covering must also be quite flexible and expandable and may limit the ability of the stent structure to expand.

Another problem with stent/grafts is the concern for tearing of the outer covering during placement and then again during expansion when implanting. Since the outer covering has to flex and expand with the expanding supporting structure, there is a risk of tearing during these operations. Tearing may result as the material itself yields or from an uneven or otherwise inefficient expansion of the underlying supporting structure which stresses or directly tears the covering. The problem is particulary a concern with stents having a supporting structure whose members must move apart circumferentially or move unevenly during expansion of the stent. Thus, there is a need for a stent and stent/graft having a supporting structure where adjacent members are very flexible and yet do not move apart considerably during expansion. There is also a need for such a supporting structure which expands uniformly.

Thus, there is a need for a stent or stent/graft which is uniformly expandable and which minimizes any high areas of stress on the outer covering during flexing and expansion, as well as for such a stent which is inexpensive and simple to install. Additionally, a need exists for a surgical device which can perform angioplasty and implant a stent within the same operation and without removing the angioplasty device. Such a surgical device should be inexpensive and operate similarly to existing angioplasty and stent implantation devices.

Summary

The present invention overcomes the aforementioned problems by providing a stent which transfers a uniform axial and radial stress on an encircling polymer coating as the stent or graft is expanded and implanted within

a body lumen. By providing a stent having a supporting structure which radially expands uniformly from a contracted condition to an expanded condition, the stress imparted into the surrounding coating is evenly distributed. This even distribution of stress allows the use of a less flexible or stronger coating while reducing the concern for tearing or other damage. For purposes of this disclosure, the term "stent" shall mean endoprostheses, and shall include stents structures and stent/grafts.

The present invention also satisfies the need for a stent having sufficient longitudinal strength to retain its implanted shape and support the polymer coating while remaining sufficiently flexible to be maneuvered into and through a tortuous body passageway. By providing a stent supporting structure having a plurality of uniformly expandable cylindrical bands, the present stent remains longitudinally flexible and supportive of the polymer coating. By providing a number of linking members which extend between and interconnect each adjacent pair of cylindrical bands, the longitudinal strength and memory are increased. Positioning each circumferential set of linking members in quadrature positions furthers increases the longitudinal strength and memory while yielding high flexibility.

The present invention also satisfies the need for a stent delivery and implantation device which can also be used to perform angioplasty procedures. By providing a balloon catheter stent implantation device having an angioplasty balloon and capable of receiving and implanting the stent of the present invention, a surgeon can effectively perform angioplasty and implant the supportive stent in a single procedure and using the single device. This eliminates the time, cost and unnecessary risk of removing the angioplasty device from the passageway and reinserting a prior art style stent deployment device.

The present invention is generally directed to a flexible stent which may be placed within a vascular conduit and is radially expandable from a contracted condition to an expanded condition. The stent includes a tubular supporting structure which has a longitudinal axis that extends between a proximal end and a distal end. The supporting structure is formed from a plurality of spaced apart

flexible cylindrical bands that extend around the longitudinal axis. Each of the cylindrical bands comprises a continuous and repeating pattern and is formed in a partially expanded condition. Each of the repeating patterns includes a straight section which leads into a proximal curved section having a first radius of curvature. This proximal curved section is in turn coupled to a second straight section which in turn leads into a distal curved section having a second radius of curvature. The repeating pattern of the cylindrical bands is configured such that each of the relatively independent cylindrical bands expands uniformly from the contracted condition to the expanded condition .

A porous surface surrounds and encapsulates at least a portion of the supporting structure between the proximal end and the distal end. The porous surface is made from a thin coating of an expandable polymer which includes a plurality of spaced apart micropores. The coating is formulated and configured to expand along with the supporting structure and also support tissue within the passageway.

In another aspect of the present invention, the flexible stent further includes a pair of spaced apart interconnecting members or links which extend between and interconnect each pair of adjacent cylindrical bands. The interconnecting members are diametrically opposed between adjacent cylindrical bands. In addition, the spaced apart interconnecting members between successive pairs of adjacent cylindrical bands are rotated 90 degrees about the longitudinal axis relative to adjacent interconnecting members. Each of the interconnecting members extends between and interconnects one of the proximal curved sections on a first cylindrical band to an adjacent distal curved section on a second and adjacent cylindrical band.

The present invention is also directed to a balloon catheter and stent implantation device for inserting and implanting a stent having an expandable supporting structure within a vascular or other body conduit. The balloon catheter device includes a tubular catheter body which has a longitudinal axis that extends between a proximal end and a distal end. The tubular body also contains a longitudinal lumen which extends distally from the proximal end. An elongate

inner member may be disposed coaxially within the catheter body for slidably supporting a catheter guidewire.

An expandable balloon is disposed coaxially about the catheter body adjacent the distal end. The balloon includes an outer balloon surface and an inner balloon surface defining a balloon chamber. The balloon chamber is fluidly connected to the lumen extending through the catheter body and is expandable between an inflated condition and a deflated condition through passage of a fluid or gas therethrough.

An independent outer sleeve is slidably supported on the catheter body. The outer sleeve includes a proximal sleeve end which extends distally to a distal sleeve tip. The distal sleeve tip is configured to engage with a stent inserted over the catheter body and to move the stent distally along the catheter body to a deployment position over the balloon. In particular, the distal sleeve tip includes an engagement groove for retaining a proximal end of said stent. Alternatively, the distal sleeve tip may be coupled to an integral retaining tube which surrounds and retains the stent against the catheter body.

An actuating mechanism is coupled to the proximal end of the elongate catheter body. The actuating mechanism includes an actuating shaft which has a proximal shaft end that is coupled to an actuating handle and a distal shaft end which is coupled to the outer sleeve. The shaft is slidable along the catheter body for slidably moving the outer sleeve along the catheter body between a proximal sleeve position and a distal sleeve position. The shaft travel is limited by a mechanical stop which prevents the outer sleeve from moving distally beyond the balloon. Thus, when fully actuated, the outer sleeve and the stent are moved distally along the catheter body until the outer sleeve reaches the distal sleeve position and the stent is positioned over the deflated balloon.

In another aspect of the present invention, the balloon catheter device includes an angioplasty balloon. The angioplasty balloon is configured for both performing angioplasty within the vascular conduit and for receiving and implanting the stent. In this aspect, the balloon catheter device eliminates the time, cost and unnecessary risk of removing the angioplasty device and

reinserting a prior art style stent deployment device when implantation of a stent is desired.

In yet another aspect of the present invention, the balloon catheter and stent delivery device includes a stent having an expandable supporting structure, such as the stent of the present invention. The stent is fitted over the catheter body and is slidably supported on the catheter body.

A preferred method for implanting a radially expandable stent within a vascular conduit or other body passageway according to the principles of the present invention comprises the steps of providing a balloon catheter stent delivery device which includes a tubular catheter body supporting an expandable balloon as previously described. An expandable stent, as previously described is also provided.

The method includes the step of placing the stent over the catheter body. After the stent is placed on the catheter body, it is compressed around the body to minimize its overall outer diameter. The catheter body, including the stent, is then inserted into the vascular conduit or other passageway of the patient and the balloon is directed to a desired location within the passageway.

After the balloon is located at the desired position, the actuating mechanism is actuated to move the outer sleeve distally along the catheter body such that the stent is pushed over and onto the deflated balloon. The balloon is then inflated to the expand the stent to the expanded condition within the passageway. Once the stent has been expanded within the passageway, the balloon is the deflated and the balloon catheter and stent delivery device is withdrawn and removed from the patient.

In another aspect of the present method, the balloon is an angioplasty balloon. In this aspect of invention, the method includes the steps of inflating and deflating the balloon to perform angioplasty within the vascular conduit prior to the step of actuating the actuating mechanism to move the stent.

This invention, together with the additional features and advantages thereof, which is only summarized in the foregoing passages, will become more apparent to those of skill in the art upon reading the description of the preferred

embodiments, which follows in the specification, taken together with the following drawings.

Brief Description of The Drawings

FIG. 1 is a partial cross-sectional view of a stent and a balloon catheter stent delivery device of the present invention shown being inserted within a patient;

FIG. 2 is an enlarged side view, in isolation, of the stent of FIG. 1;

FIG. 3 is a cross-sectional view of the stent of FIG. 2 taken along lines 3-3;

FIG. 4 is a side view of an alternative embodiment of a supporting structure according to the principles of the present invention;

FIG. 5 is a cross-sectional view of the supporting structure of FIG. 4, taken along lines 5-5;

FIG. 6 is a partial side view of a second alternative embodiment of the supporting structure according to the principles of the present invention;

FIG. 7 is a perspective view of the balloon catheter and stent device of FIG. 1;

FIG. 8 is an elevational side view of a compression device for use in compressing the stent of the present invention over a catheter device;

FIG. 9 is an expanded and partial-elevational side view showing a stent of the present invention compressed on a portion of a balloon catheter device; and

FIG. 10 is a cross-sectional view of the stent and balloon catheter device of FIG. 9 taken along lines 10-10.

Description of the Preferred Embodiments

Referring now to the drawings, wherein like reference characters designate identical or corresponding parts throughout the several views and embodiments, a radially expandable stent and a balloon catheter and stent delivery device according to the principles of the present invention are illustrated in Figure 1 and designated by the reference numerals 10 and 12, respectively.

As shown, the stent 10 is mounted on the balloon catheter device 12 for insertion within a body passageway 14 of a patient (not shown). The body passageway 14 may include most any body passageway, including a vascular conduit such as an artery, a vessel or a vein. The stent 10 may also include a stent/graft or similar tubular intraluminal prosthetic or endoprostheses device.

Referring now to Figures 2-6, the stent 10 includes a flexible and tubular supporting structure 18. The supporting structure 18 has a longitudinal axis 20 which extends between a proximal end 22 and a distal end 24. The supporting structure 18 is formed from a plurality of spaced apart and relatively independent flexible cylindric bands 26. Each of these cylindrical bands 26 extends around the longitudinal axis 20 and is radially expandable from a contracted condition 28 to an expanded condition 30.

Each of the cylindrical bands 26 is formed from a continuous and repeating pattern 32. Preferably, this repeating pattern 32 sequentially and circumferentially includes a straight section 34 which leads into a proximal curved section 36 having a first radius of curvature 38. The proximal curved section 36 in turn, leads into a second straight section 40 which is itself joined to a distal curved section 42 having a second radius of curvature 44. The proximal curved section 36 and the distal curved section 42 may have a uniform curve or bend to facilitate the uniform radial expansion of the cylindrical band 26 from the contracted condition 28 to the expanded condition 30. Preferably, the first radii of curvature 38 and the second radius of curvature 44 are the same, however, differing radii of curvature may also be used.

The sections 34, 36, 40 and 42 of the supporting structure 18 each have a cross section 46 which is preferably rectangular shaped with rounded corners, as best illustrated in Figure 5. However, the cross section 46 of the supporting structure 18 and particularly, the individual sections 34, 36, 38 and 42, may also be formed into other shapes, such as circular, ellipse, oval, or egg, for example.

At least one linking member 48 may be provided between at least one pair of adjacent cylindrical bands 26. The linking member 48 may extend between and interconnect the two adjacent cylindrical bands 26. Preferably, each pair of

adjacent cylindrical bands 26 is interconnected with a plurality or group of linking members 48 which are spaced apart around their circumferences. Each of the linking members 48 may extend and interconnect the proximal curved section 36 on a first cylindrical band 52 to the adjacent distal curved section 42 on a second and adjacent cylindrical band 56 as best illustrated in Figures 4 and 6.

Successive pairs of adjacent cylindrical bands 26 may be interconnected with a set of linking members 48 with adjacent sets of linking members 48 indexed or rotated relative to the longitudinal axis 20. This indexing alters the positions of the linking members 48 between each successive pair of cylindrical bands 26 relative to adjacent pairs of linking members 48, thus improving the flexibility of the stent 10 while maximizing structural strength and memory.

In a preferred embodiment, two linking members 48 are positioned between each pair of adjacent cylindrical bands 26 as described above. The linking members may be straight links which are generally parallel with the longitudinal axis 20. Each set of the two linking members 48 are equally spaced apart around the circumference of the adjacent cylindrical bands 26. Thus, the linking members 48 are diametrically opposed between each pair of adjacent cylindrical bands 26 (preferably 180 degrees apart). In addition, each set of the linking members 48 between successive pairs of adjacent cylindrical bands 26 is rotated 90 degrees about the longitudinal axis 20 relative to the adjacent pair of linking members 48. This pattern of positioning the linking members 48 in a quadrature orientation around the circumference of the cylindrical bands 26 improves articulation and flexibility and is best illustrated in Figure 4, where the ends of each cylindrical band 26 at the top of the figure is understood to be connected to and continuous with the respective cylindrical band 26 at the bottom of the figure (this is also represented in Figure 6 as; a-a, and b-b).

Alternatively, the linking members 48 may have a sinusoidal-shape 57, as best illustrated in Figure 6. This type of link structure 57 may be preferred where it is desired to maintain a strongly bent shape retention characteristic or memory from the insertion and deployment procedure, while allowing for substantial

flexing properties as the stent 10 is being inserted through the vascular conduit or other passageway 14.

As discussed, the linking members 48 provide structural strength to the stent 10 as well as modifying its overall flexibility. Varying the number, placement, shape and size of the linking members 48 will particularly increase or decrease the flexibility of the stent 10 along the longitudinal axis 20. This flexibility is important because the stent 10 must flex when mounted on the shaft of the catheter delivery device 12 as the shaft is advanced through the vascular system and into a desired location. Further, the desired location where the stent 10 is to be implanted may be a complex curve or alternatively may be a straight segment. Thus, the desired flexibility of the stent 10 may be tailored to the specific application.

Maximum flexibility may typically be achieved by eliminating the linking members 48 altogether. However, a potential disadvantage for some applications will be that the stent 10 will have a lack of memory and want to return to a neutral position after being flexed, rather than maintaining a bent shape into which it has been conformed by the catheter delivery device 12 during the insertion procedure. In other applications, maximum flexibility may be advantageous, if for example, the stent 10 is desired to flex with the vessel during the expansions and contractions of the heart. Thus the selection of the number, placement, shape and size of the linking members 48 may be tailored for each specific application.

The stent supporting structure 18 may be machined from a section of surgical grade tubing material. Machining may include laser machining or even chemical machining, including chemical etching. The supporting structure 18 may also be fabricated from a continuous or alternatively, discrete segments of a metal wire which are formed into a plurality of columns of the repeating pattern 32, as is best illustrated in Figure 4. The formed wire may be shaped into the cylindrical bands 26 by bending the wire over forming mandrels and welding or otherwise connecting the wires to form the continuous cylindrical bands 26.

The supporting structure 18 is preferably constructed in an intermediate expanded condition. Thus, the supporting structure 18 is preferably constructed using tubing or a mandrel or similar device having a cross sectional diameter greater than the diameter of the structure in the contracted state 28 but smaller than the diameter of the structure in its expanded state 30. Constructing the supporting structure 18 with an intermediate expanded state allows more uniform expansion to the expanded state 30 as well as more uniform compression to the contracted state 28.

The supporting structure 18 and particularly, the tubing material may be constructed from a surgical grade metal tubing such as a stainless steel or tantalum hypotube. However, other materials may also be used and may include: platinum, titanium, nitinol, or even a high strength polymer or other plastic. In a preferred embodiment, the structural support 18 is made from a 315L stainless steel hypotube, of approximately 0.5 to approximately 3.0 mm diameter and a wall thickness of between approximately .001 to approximately .005 inches. However, other sizes and thicknesses may also be used. A self-expanding spring material may also be used.

The stent supporting structure 18 may be further processed after machining, welding or any other fabrication step to eliminate any rough surfaces or sharp corners. This processing step may also be used to shape the cross section 46 of the sections 34, 36, 40 and 42. Processing may include sand blasting, chemical deburring, etching or any other similar process.

A portion of the stent supporting structure 18 may be encapsulated with a thin flexible coating or covering 58, as illustrated in Figures 2 and 3. Preferably, the thin coating 58 includes a plurality of spaced apart micropores 60. The coating 58 may be made from a polymer, such as a bio-compatible polyurethane, however, any bio-compatible and flexible material may be used. Preferably, the coating 58 is formulated and applied to the supporting structure 18 such that it is expandable with the supporting structure 18. The coating 58 may also be used as a carrier for supporting therapeutic agents and drugs.

A suitable coating mixture for dipping and forming the coating 58 may be formulated by dissolving a medical grade aliphatic polyurethane such as Tecoflex 5680, manufactured by Thermedics Co of Woburn, Massachusetts, in pyrolidone solvent at approximately 3% solids by weight. A number of suitable polymers, including polymers containing a therapeutic drug, which may be used as the coating material 58 are described in U.S. Patent No. 5,591,227, and issued to Dinh, which is herein expressly and fully incorporated by reference. A suitable polyurethane is also described in U.S. Patent Serial No. 4,873,308, which is also herein expressly incorporated by reference. Suitable solvents may include, for example, tetrahydrofuran, methylene chloride, trichloromethane, idoxane, and dimethyl formamide.

The thin coating 58 may be formed on the supporting structure 18 by dipping the supporting structure 18 into a suitable biocompatible synthetic or naturally-occurring coating material 58, such as the polymer materials described above and which has been dissolved in a compatible solvent. In particular, the stent supporting structure 18 may be secured by at least one of the proximal or distal ends 22 and 24. A mask may be used to prevent the coating 58 from being applied to specific locations on the supporting structure 18. Preferably, the stent 10 is configured having the proximal end 22 and the distal end 24 free from the encapsulating coating 58. Thus, the mask may be placed over the proximal and distal ends 22 and 24 and anywhere else that the coating 58 is not desired.

The supporting structure 18 may then be dipped into the polymer and solvent mixture to coat and encapsulate the unmasked portion. Multiple dips or other applications of the polymer and solvent may be required to achieve the desired coating thickness. The number of dips required may vary depending on the viscosity of the polymer and solvent mix and the size of the supporting structure 18. Preferably, the coating 58 may have a wall thickness of approximately .001-.015 inches. The mask may then be removed.

In an alternative method of applying the coating 58, the stent supporting structure 18 may be placed over a separate holding structure which has an outer cylindrical surface. Such a holding structure may simply be a dowel type pin, but

preferably includes an outer surface made from a non stick material such as a Teflon. The holding structure and attached supporting structure 18 may then be advanced through a tube coating machine for application of the coating 58. The use of a supporting member and a tube coating machine is generally described in U.S. Patent No. 4,356,218, issued to Chiu et al., and herein expressly and fully incorporated by reference. Other methods, of applying the coating 58 may also be used and may include folding a semi-solid layer of the coating 58 around the supporting structure 18, or shrinking a polymer tube over the supporting structure 18.

To create the micropores 60 within the resulting coating 58, soluble particles such as sugar or salt may be added to the solution of polymer and solvent. The particles are preferable maintained suspended by continuous stirring or mixing. After application of the coating 58, the stent 10 may be dipped in water or other solvent to dissolve the particles from the polymer matrix, leaving the micropores 60. Alternatively, the micropores 60 may be created or formed using any method as is commonly known in the fabrication of polymer coatings and stents. Preferably, the micropores 60 may be from a few microns in diameter to the approximate size of sand grains, however, larger as well as smaller sized micropores 60 are contemplated and may be used.

The supporting structure 18, and preferably, only the portion of the supporting structure 18 which is not encapsulated by the thin coating 58, may be further processed to form a porous exterior surface 62. In particular, the supporting structure 18 may be coated with microbeads or similar particles to create the porous exterior surface 62. U.S. Patent Serial No. 4,101,984, issued to MacGregor, discloses suitable microbeads and methods of processing to attach these microbeads to a structure, and is herein expressly and fully incorporated by reference. The porous exterior surface 62 renders the exposed portions of the supporting structure 18, such as the proximal and distal ends 22 and 24, more biocompatible by promoting tissue in-growth while reducing the formation of blood clots.

Referring now to Figure 7, the balloon catheter and stent delivery device 12 may be used to insert a radially expandable tubular stent and particularly, the stent 10 of the present invention, within the body passageway 14 and deliver it to the desired location. The balloon catheter device 12 includes an elongate tubular catheter body 64 which has a longitudinal catheter axis 66 extending between a proximal catheter end 68 and a distal catheter end 70. The catheter body 64 may contain an internal longitudinal lumen which extends distally from the proximal catheter end 68. An elongate inner member may be disposed coaxially within the catheter body 64 for slidably supporting a catheter guidewire.

An expandable balloon 72 is disposed coaxially about the catheter body 64 adjacent the distal catheter end 70. The balloon 72 includes an outer balloon surface 74 and an inner balloon surface which defines an interior balloon chamber. The balloon chamber may be fluidly connected to a lumen 73 which extends longitudinally through the catheter body 64. A fluid or a gas may then be passed through the lumen 73 to inflate and deflate the balloon 72 between an inflated condition and a deflated condition.

The balloon 72 is configured to receive the tubular stent 10 when in the deflated condition, as best illustrated in Figure 7. The stent 10 may be inserted over the deflated balloon 72 or alternatively over the catheter body 64 where it may be later moved over the deflated balloon 72. The balloon 72 may then be inflated or otherwise expanded such that the stent 10 is radially expanded within the bodily passageway 14. Preferably, the balloon 72 is a high pressure dilation balloon.

In a preferred embodiment of the balloon catheter device 12, the balloon 72 may be an angioplasty balloon. The angioplasty balloon 72 is preferably configured for both performing angioplasty within the body passageway 14 which may be a vascular conduit and for receiving and implanting the stent 10. The outer surface 74 of the angioplasty balloon 72 may expand uniformly parallel to the catheter longitudinal axis 66 such that the stent 10 may be uniformly expanded in the radial direction. The use of a single device, such as the present balloon catheter device 12, eliminates the time, cost and unnecessary risk of

removing a specific angioplasty device and reinserting a specific stent deployment device.

An independent outer sleeve 76 is movably mounted on the catheter body 64. Preferably, the outer sleeve 76 is slidably supported along the longitudinal length of the catheter body 64 and may have a cross section which slidably mates over the cross section of the catheter body 64. The outer sleeve 76 includes a proximal sleeve end 78 which extends distally along the catheter body 64 to a distal sleeve tip 80. The distal sleeve tip 80 may be configured to engage with a stent 10 that has been inserted over and onto the catheter body 64 and to move the stent 10 distally along the catheter body 64 to a deployment position over the balloon 72. The outer sleeve 76 may be constructed from a plastic, such as an extrudable or moldable polymer. However, other materials may also be used.

The distal sleeve tip 80 may include an engagement device 82 for receiving and retaining the stent 10 against the catheter body 64. Specifically, the engagement device 82 may be a circumferential groove or even a series of grooves or depressions formed within the distal sleeve tip 80. This engagement groove 82 is used to receive and retain or cup the stent proximal end 22 while the stent 10 is moved distally along the catheter body 64. The engagement groove 82 may be particularly useful to retain or cup the plurality of stent tips 25 (proximal curved sections 36) on the stent proximal end 22 and prevent them from being bent inwardly or outwardly relative to the catheter body 64 during insertion and deployment.

Alternatively, the engagement device 82 may include an integral retaining tube which is coupled to the distal sleeve tip 80. The integral retaining tube 82 may be preferable when inserting and deploying a stent 10 having a supporting structure 18 made from a self expanding material. The integral retaining tube 82 may be moved over the stent 10 after placement on the catheter body 64 to maintain the stent 10 in the contracted condition 28. Alternatively, the retaining tube type of engagement device 82 may include a slidable or removable sheath which is placed over the stent 10 and coupled to the outer sleeve 76.

Once the stent 10 has been moved or slid into position over the balloon 72, the retaining tube type of engagement device 82 may be removed. Removal may be accomplished by inflating the balloon 72 to rupture the engagement device 82. Alternatively, removal may be accomplished by tearing and removing the tube 82 during proximal pullback of the outer sleeve 76 while holding the stent 10 with the balloon 72. A tether or other retaining strap may be attached to the retaining tube type of engagement device 82 and also secured to the balloon catheter device 12 to ensure its removal from the body passageway 14. The retaining tube device 82 may also include an integral, tear-away strap which is attached to the outer sleeve 76. In this configuration, pulling proximally on the outer sleeve 76 after positioning the stent 10 over the balloon 72 may cause the tube device 82 to tear along it's longitudinal axis, thus releasing the stent 10.

An actuating mechanism 84 may be coupled to the catheter proximal end 68 for use in moving the outer sleeve 76 along the catheter body 64 between a proximal sleeve position 86 and a distal sleeve position 88. The actuating mechanism 84 may also be coupled to a hub 90, such as a tri-furcated hub or similar device, which may be directly attached to catheter proximal end 68.

The actuating mechanism 84 may be configured to include an actuating shaft 92 which may be generally parallel to, and slidable along or alternatively within, the catheter body 64. The actuating shaft 92 may include a proximal shaft end 94 which is connected to an actuating handle 96 or other grip and a distal shaft end 98 which is coupled to the outer sleeve 76. An intermediate coupling 99 or pusher sleeve may be used to couple the shaft 92 to the outer sleeve 76. The shaft 92 is slidable by moving the handle 96 relative to the catheter body 64 to slidably move the outer sleeve 76 between the proximal sleeve position 86 and the distal sleeve position 88. The actuating shaft 92 may be constructed from a stainless steel wire or other high strength and flexible material such as nininol, a liquid crystal polymer, or even Marlex. However, other materials may also be used.

Movement of the handle 96 or even the shaft 92 relative to catheter body 64 may be limited by a mechanical stop 100 which prevents the outer sleeve 76 from moving the stent 10 distally beyond the balloon 72. Thus, when the actuating mechanism 84 is fully actuated, the outer sleeve 76 and the stent 10 are moved distally along the catheter body 64 until the outer sleeve 76 reaches the distal sleeve position 88 and the stent 10 is positioned over the deflated balloon 72. The mechanical stop 100 may include limiting the length of the shaft 92 or the travel of the handle 96. A marking or indicator may also be placed on the shaft 92 or even the catheter device 12 to indicate the location of the outer sleeve 76 and thus the stent 10 relative to the proximal and distal sleeve positions 86 and 88.

Referring now to Figures 1-10, a method of using a stent delivery device, such as the balloon catheter device 12 of the present invention to insert and implant a radially expandable stent, such as the stent 10 of the present invention, into a desired location 16 within a body passageway 14 will be described. The method, which restores or otherwise improves the patency of a body lumen, includes the step of providing a balloon catheter stent delivery device, such as the balloon catheter device 12 previously described.

A radially expandable stent, such as the stent 10 to the present invention is provided. The stent 10 is placed over the catheter body 64 and adjacent the outer sleeve 76. The stent 10 may then be compressed on the catheter body 64. This step of compressing the stent 10 onto the catheter body 64 may be accomplished using a conical compression fixture 102 , as best illustrated in Figure 8. Preferably, the stent 10 is compressed snugly against the catheter body 64 such that it does not freely move, but is generally freely movable when pushed by the outer sleeve 76. Figure 9 shows the stent 10 compressed about the catheter body 64.

The actual step of compression may be accomplished by sliding a flexible tube 104 over the partially expanded stent 10, as best illustrated in Figure 8. The tube 104 and the contained stent 10 may then be slid or otherwise moved through the enlarged open end 106 of the conical compression fixture 102 and drawn

through its gradually decreasing diameter such that the stent 10 is compressed against the catheter body 64. The flexible tube 104 may then be removed from the catheter body 64 and the stent 10. Preferably, the flexible tube 104 comprises an elastomeric and preferably a fluropolymer sleeve or similar material tube. Note, that if the stent 10 is made from a self-expanding material as previously discussed, the step of compressing may also include the step of applying a tube or sheath, such as the retaining tube type engagement device 82 about the compressed stent 10. Alternative methods of compressing the stent 10 over the catheter body 64 may also be used and may include stent crimping tools or even manual crimping.

During the compression step, the polymer coating 58 over the unsupported regions 45 within the supporting structure 18 is preferably smoothly displaced towards the longitudinal axis 20 of the stent 10, as best illustrated in Figure 10. These openings or unsupported regions 45 become smaller as the cylindrical bands 26 are uniformly circumferentially compressed about the catheter body 64. The resulting displacement of the thin polymer coating 58 creates a series of axially oriented ridges 108 of the polymer coating 58. These ridges 108 may be further compressed upon contact with the catheter body 64 to clamp and secure the stent 10 in a fixed location on the catheter body 64.

With the stent 10 now placed on the catheter body 64 and preferably adjacent the outer sleeve 76, the catheter body 64 may be inserted into the body passageway 14 of the patient. Once inside the body passageway 14, the catheter body 64 and particularly, the balloon 72 are placed at the desired location 16 within the passageway 14.

Once positioned, the balloon 72, which is preferably an angioplasty balloon as previously described may be inflated to dilate the body passageway 14 and more preferably, to perform angioplasty. The balloon 72 may be further inflated and deflated along with any other desired angioplasty techniques as are known in the art of angioplasty.

After the body conduit 14 has been suitably dilated by the balloon 72, the balloon 72 is deflated and the actuating mechanism 84 is actuated to move the

outer sleeve 76 and the adjacent stent 10 distally along the catheter body 64. Preferably, the actuating mechanism 84 is advanced, or otherwise actuated, a predetermined distance such that the stent 10 is pushed over and centrally located on top of the deflated balloon 72. Once the stent 10 is positioned on the balloon 72, the balloon 72 is inflated to uniformly and smoothly expand the supporting structure 18 and the surrounding polymer coating 58. Preferably, the stent 10 is expanded into the expanded state 30 and implanted within the body passageway 14 to support the dilated passageway 14. The balloon 72 may then be deflated and the balloon catheter device 12 withdrawn from the patient.

It will be understood that various modifications can be made to the various embodiments of the present invention herein disclosed without departing from the spirit and scope thereof. For example, various sizes of the stent and the balloon catheter and delivery device are contemplated as well as various types of construction materials. Also, various modifications may be made in the configuration of the parts and their interaction. Therefore, the above description should not be construed as limiting the invention, but merely as an exemplification of preferred embodiments thereof. Those of skill in the art will envision other modifications within the scope and spirit of the present invention as defined by the claims appended hereto.

WHAT IS CLAIMED IS:

1. A flexible stent for placement within a vascular conduit and radially expandable from a contracted state to an expanded state, the flexible stent comprising:

a tubular supporting structure having a longitudinal axis extending between a proximal end and a distal end, said supporting structure having a plurality of spaced apart cylindrical bands extending around said longitudinal axis, each of said plurality of bands having a continuous and repeating pattern, said repeating pattern having a straight section leading into a proximal curved section having a first radius of curvature and leading into a second straight section which leads into a distal curved section having a second radius of curvature;

a plurality of linking members extending between and interconnecting a pair of adjacent cylindrical bands, said linking members extending between and interconnecting one of the proximal curved sections on a first cylindrical band to an adjacent distal curved section on a second and adjacent cylindrical band, and wherein said linking members are equally spaced apart about the circumference of the adjacent cylindrical bands;

a porous surface surrounding at least a portion of said supporting structure between said proximal end and said distal end, said surface being expandable with said supporting structure; and

wherein each of said cylindrical bands expands uniformly from said contracted state to said expanded state.

2. The flexible stent as recited in claim 1 wherein said porous surface comprises a thin coating.

3. The flexible stent as recited in claim 1 wherein each of the plurality of equally spaced apart linking members extending between and

interconnecting successive pairs of cylindrical bands are indexed 90 degrees about the longitudinal axis.

4. The flexible stent as recited in claim 1 wherein each of the plurality of linking members between each pair of adjacent cylindrical bands comprises two equally spaced apart and diametrically opposed linking members and wherein adjacent pairs of cylindrical bands have said two linking members aligned in quadrature positions between successive cylindrical bands.

5. The flexible stent as recited in claim 1 wherein the first radius of curvature and the second radius of curvature are the same.

6. The flexible stent as recited in claim 1 wherein said porous surface comprises a plurality of micropores.

7. The flexible stent as recited in claim 2 wherein said thin coating comprises a polymer.

8. The flexible stent as recited in claim 7 wherein said thin coating comprises a biocompatible polyurethane.

9. The flexible stent as recited in claim 1 wherein said supporting structure comprises a stainless steel.

10. The flexible stent as recited in claim 1 wherein at least one section of said supporting structure comprises a cross section having a generally rectangular shape.

11. The flexible stent as recited in claim 1, and further comprising a plurality of microbeads attached to said supporting structure.

12. A balloon catheter device for inserting a tubular stent having a radially expandable supporting member within a vascular conduit, said balloon catheter comprising:

a tubular catheter body having a longitudinal axis extending between a proximal end and a distal end;

an expandable balloon disposed coaxially about the catheter body adjacent said distal end, said balloon having an outer balloon surface and an inner balloon surface defining a balloon chamber, said balloon being expandable between an inflated condition and a deflated condition;

an outer sleeve having a proximal sleeve end and a distal sleeve tip, said sleeve being slidably supported by said catheter body for moving said stent distally along said catheter body and over said balloon when said balloon in said deflated condition; and

an actuating mechanism coupled to the proximal end of said catheter body, said actuating mechanism attached to said outer sleeve for slidably moving said outer sleeve along said tubular body between a proximal sleeve position and a distal sleeve position.

13. The balloon catheter device as recited in claim 12 wherein said distal sleeve tip comprises an engagement groove for retaining a proximal end of said stent.

14. The balloon catheter device as recited in claim 12, and further comprising an integral retaining tube coupled to said distal sleeve tip for retaining said stent against said catheter body.

15. The balloon catheter device as recited in claim 12 wherein said balloon is an angioplasty balloon.

16. The balloon catheter device as recited in claim 12 wherein the actuating mechanism comprises an actuating shaft having a proximal shaft end

connected to a handle and a distal shaft end connected to said outer sleeve, and wherein said shaft is slidable along said catheter body.

17. The balloon catheter device as recited in claim 16 wherein said actuating mechanism comprises a mechanical stop for limiting the longitudinal movement of the outer sleeve relative to the catheter body such that the stent is positioned on the balloon when the actuating mechanism is moved to a distal position.

18. The balloon catheter device as recited in claim 12, and further comprising an expandable stent having a plurality of cylindrical bands encapsulated by a porous coating, said stent slidably supported by said catheter body.

19. The balloon catheter device as recited in claim 18 wherein said porous coating comprises an encapsulating thin polymer coating.

20. The balloon catheter device as recited in claim 19 wherein said stent further comprises:

a tubular supporting structure having a longitudinal axis extending between a proximal end and a distal end, said supporting structure having a plurality of spaced apart cylindrical bands extending around said longitudinal axis, each of said plurality of bands having a continuous and repeating pattern, said repeating pattern having a straight section coupled to a proximal curved section having a first radius of curvature and coupled to a second straight section coupled to a distal curved section having a second radius of curvature;

wherein the thin coating comprises a polymer coating surrounding at least a portion of said supporting structure between said proximal end and said distal end, said thin coating being expandable with said supporting structure; and

wherein each of the cylindrical bands expands uniformly from said contracted condition to said expanded condition .

21. The balloon catheter device as recited in claim 20 wherein said stent further comprises a plurality of linking members extending between and interconnecting each pair of adjacent cylindrical bands and wherein each of said linking members extends between and interconnects one of the proximal curved sections on a first cylindrical band to an adjacent distal curved section on a second and adjacent cylindrical band, and wherein said linking members are equally spaced apart about the circumference of each pair of adjacent cylindrical bands.

22. The balloon catheter device as recited in claim 21 wherein each of the plurality of equally spaced apart linking members extending between and interconnecting successive pairs of cylindrical bands are indexed 90 degrees about the longitudinal axis.

23. The balloon catheter device as recited in claim 21 wherein each of the plurality of linking members between each pair of adjacent cylindrical bands comprises two equally spaced apart and diametrically opposed linking members and wherein adjacent pairs of cylindrical bands have said two linking members aligned in quadrature positions between successive cylindrical bands.

24. The balloon catheter device as recited in claim 20 wherein the first radius of curvature and the second radius of curvature on said stent are the same.

25. The balloon catheter device as recited in claim 20 wherein said thin coating encapsulating said stent comprises a plurality of micropores.

26. The balloon catheter device as recited in claim 20 wherein said thin coating encapsulating said stent comprises a polymer.

27. The balloon catheter device as recited in claim 26 wherein said thin coating encapsulating said stent comprises a biocompatible polyurethane.

28. The balloon catheter device as recited in claim 20 wherein said supporting structure of said stent comprises a stainless steel.

29. The balloon catheter device as recited in claim 20 wherein at least one section of said stent supporting structure comprises a cross section having a generally rectangular shape.

30. The balloon catheter device as recited in claim 20 wherein said stent further comprises a plurality of microbeads attached to said supporting structure.

31. A method of implanting a radially expandable stent to a desired location within a vascular conduit of a patient, the method comprising the steps of:

providing a balloon catheter stent delivery device comprising:

a tubular catheter body having a longitudinal axis extending between a proximal end and a distal end,

an expandable balloon disposed coaxially about the catheter body adjacent said distal end, said balloon being expandable between an inflated condition and a deflated condition;

an outer sleeve having a proximal sleeve end and a distal sleeve tip, said sleeve being slidably supported on said catheter body for moving said stent distally along said catheter body and over said balloon when said balloon is in said deflated condition; and

an actuating mechanism coupled to the proximal end of said catheter body, said actuating mechanism attached to said outer sleeve for slidably moving said outer sleeve along said tubular body between a proximal sleeve position and a distal sleeve position;

providing a radially expandable stent for use with said catheter stent delivery device, said stent including a tubular supporting structure having a longitudinal axis extending between a proximal stent end and a distal stent end, said supporting structure having a plurality of spaced apart cylindrical bands extending around said longitudinal axis, each of said plurality of bands formed in a partially expanded condition and having a continuous and repeating pattern, said supporting structure surrounded by an expandable coating having a plurality of micropores;

placing the expandable stent on said catheter body adjacent said outer sleeve;

compressing the stent on the catheter body;

inserting the catheter device and the attached stent into the vascular conduit of the patient;

placing the balloon at said desired location within said vascular conduit;

actuating said actuating mechanism to move said outer sleeve distally along said catheter body such that the stent is pushed over and onto the deflated balloon;

inflating said balloon to expand said stent into said expanded condition;

deflating said balloon; and

withdrawing said balloon catheter from said patient.

32. The method as recited in claim 31 wherein the step of compressing the stent comprises the steps of:

placing a flexible tube over the partially expanded stent;

sliding the flexible tube surrounding the stent through an open conical compression fixture having a gradually decreasing diameter such that said stent is compressed against said catheter body; and

removing the elastomeric tube from over the catheter body and the stent.

33. The method as recited in claim 31 wherein the balloon is an angioplasty balloon and wherein the method further comprises the steps of:

inflating the angioplasty balloon at the desired location within the vascular conduit to perform angioplasty; and

deflating the angioplasty balloon, and

wherein said steps are performed prior to the step of actuating the actuating mechanism.

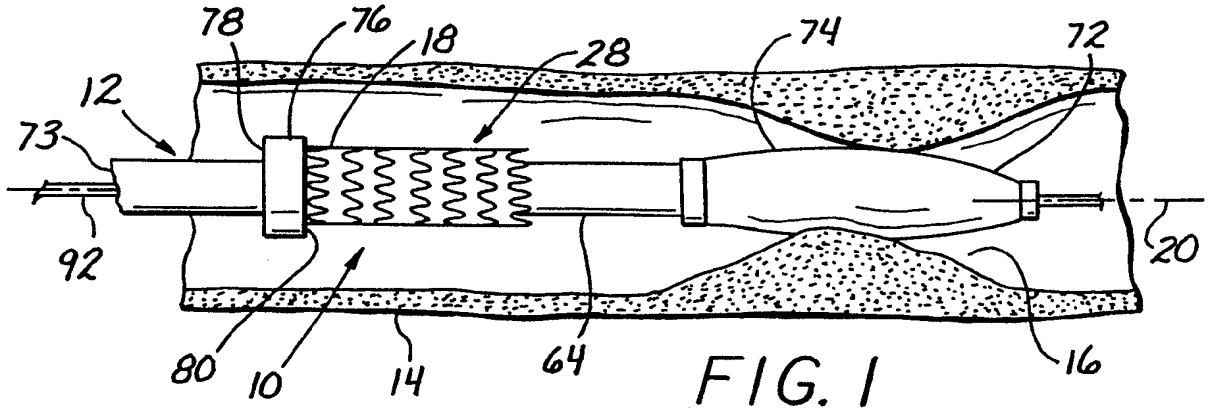


FIG. 1

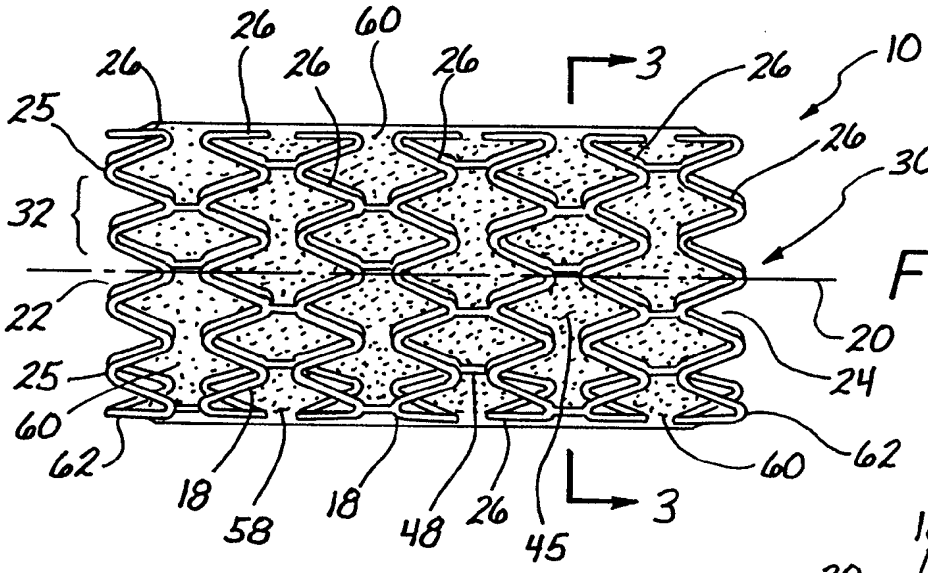


FIG. 2

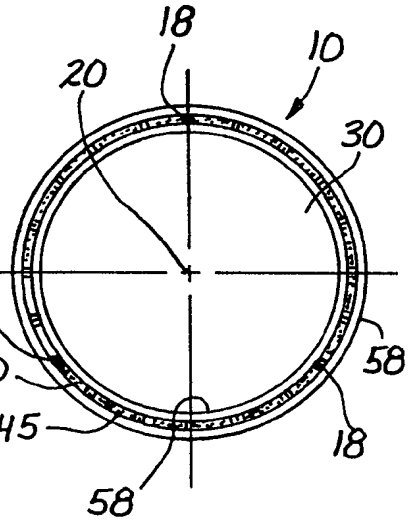


FIG. 3

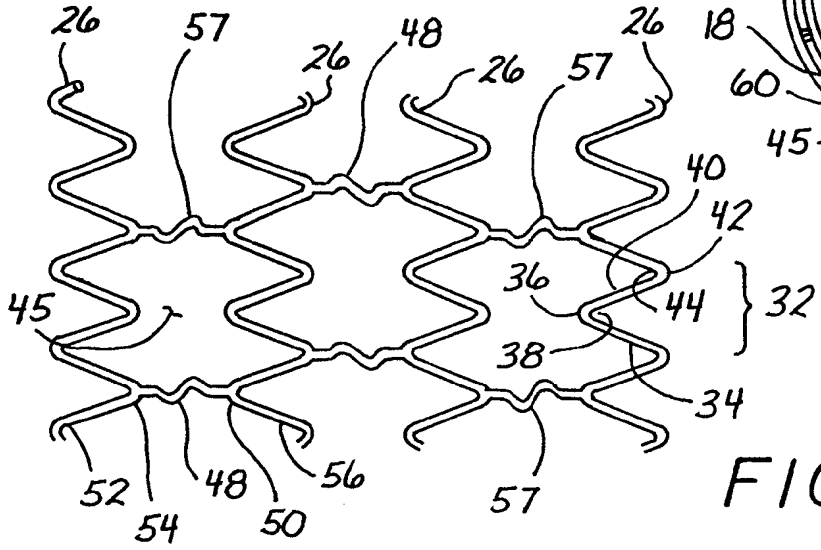


FIG. 6

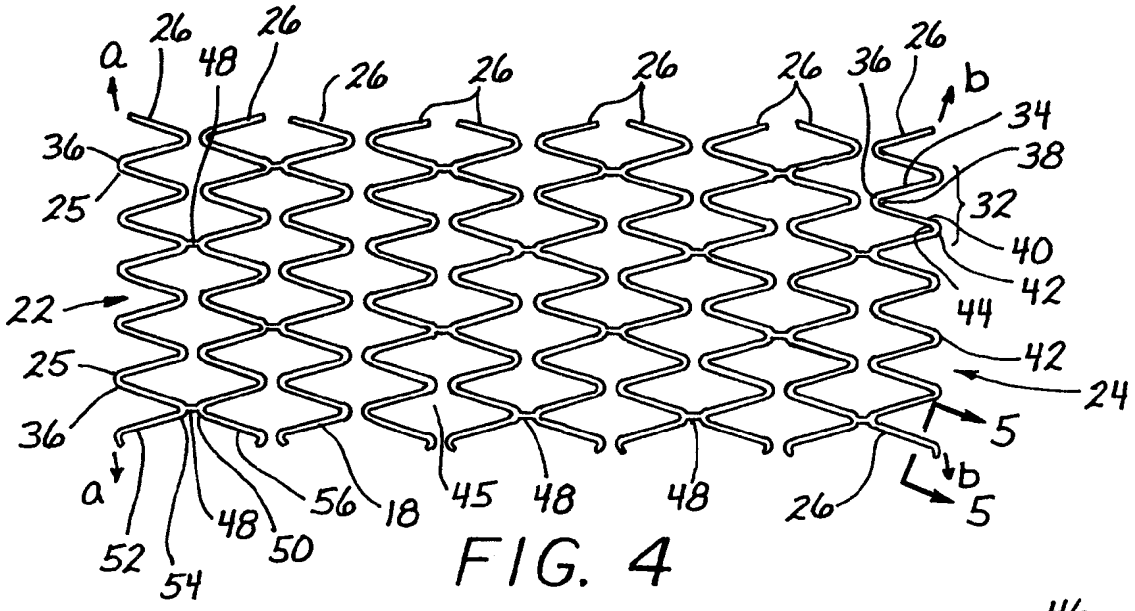


FIG. 4

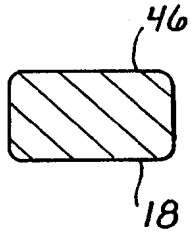
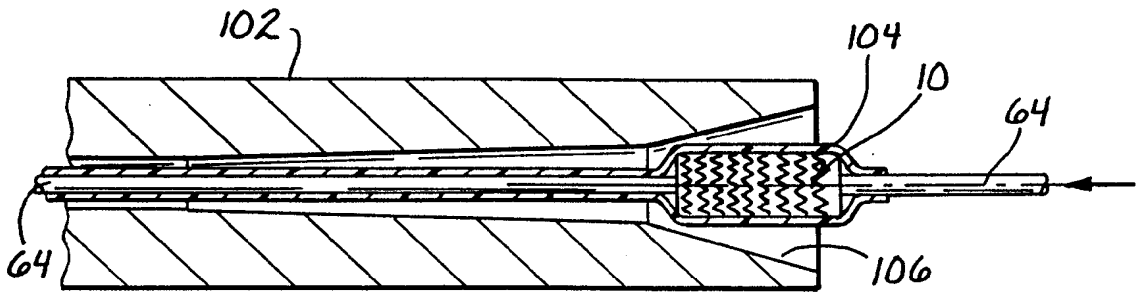


FIG. 5

FIG. 7

FIG. 8



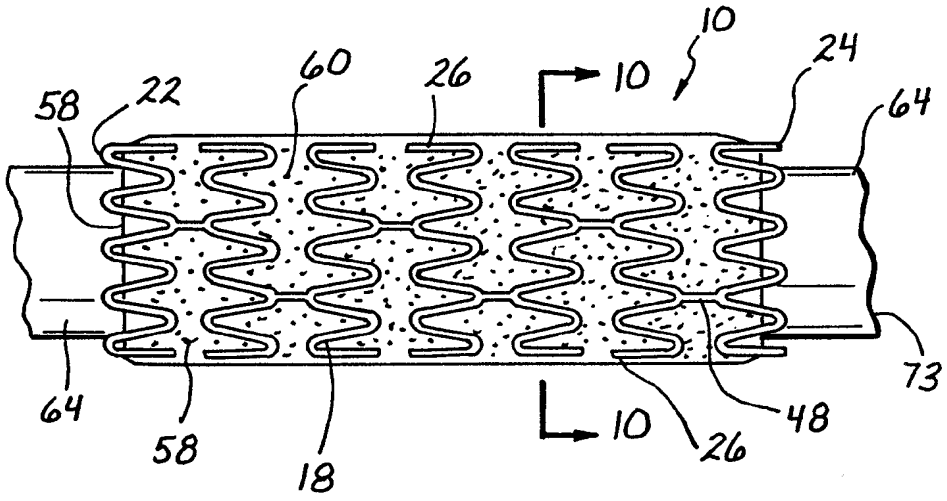


FIG. 9

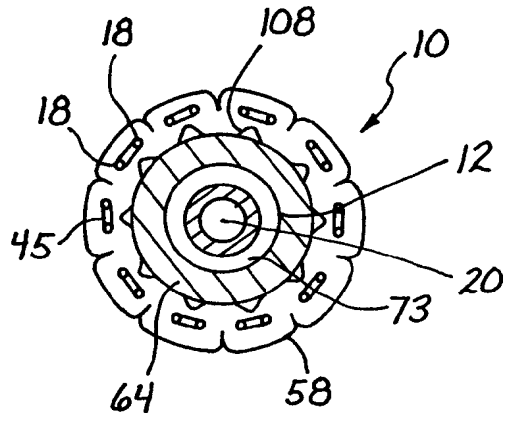


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/16514

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61F 2/04, 06; A61M 29/00
US CL :606/191, 194, 195; 623/1, 12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1, 12; 606/191, 194, 195

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS
search terms: stent, porous, coating, polymer, micropores, microbeads, balloon catheter

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,195,984 A (SCHATZ) 23 March 1993 (23.03.93), entire document.	12-17, 31-33 --- 1-10, 18-29
X --- Y	US 5,449,373 A (PINCHASIK et al.) 12 September 1995 (12.09.95), Figs. 2D-2F.	12-17 --- 1
Y	US 5,123,917 A (LEE) 23 June 1992 (23.06.92), entire document.	2, 6-8
Y	US 5,282,823 A (SCHWARTZ et al.) 01 February 1994 (01.02.94), entire document.	1
Y	US 5,591,197 A (ORTH et al.) 07 January 1997 (07.01.97), entire document.	1

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
22 OCTOBER 1998

Date of mailing of the international search report
09 NOV 1998

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